DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 26, 2014

Imaging Sciences International (dba Gendex LLC, Dexis LLC)
Sanjay Ahuja
Director of Regulatory Affairs
1910 North Penn Road
HATFIELD PA 19440

Re: K141451
Trade/Device Name: VixWin Platinum
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 1, 2014
Received: August 1, 2014

Dear Dr. Ahuja:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141451

Device Name
VixWin Platinum

Indications for Use *(Describe)*
VixWin Platinum is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

VixWin Platinum

Submitter's Name, Address, Telephone Number
Imaging Sciences International LLC (dba Gendex LLC, DEXIS LLC)
1910 North Penn Rd.
Hatfield, PA 19440

Contact Person
Sanjay Ahuja, Ph.D.
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Date Prepared
30 May 2014

Name of Device
VixWin Platinum

Name/Address of Sponsor
Imaging Sciences International (dba Gendex LLC)
1910 North Penn Rd.
Hatfield, PA 19440

Common or Usual Name
Dental Imaging Device

Product Code
LLZ

Classification Name
System, Image Processing, Radiology, per 21 CFR §892.2050.

Predicate Devices
VixWin PRO (K060178)

Intended Use / Indications for Use
VixWin Platinum is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

Caution: Federal law restricts this device to sale by or on the order of a trained and qualified dentist or dental technician.

Technological Characteristics

The following are the technological characteristics between the proposed version of Microsoft Windows (3.3) and the cleared version of the VixWin Platinum Software (K060178).

Component/ Functionality	**VixWin PRO (K060178)**	**VixWin Platinum (Proposed)**
Indication for Use	VixWin PRO controls capture, display, treatment, analysis and saving of X-ray digital images from DenOptix ® , Visualix ® /GX-S, Orthoralix9200 DPI and DDE digital imaging systems produced by Gendex. It can also handle other types of digital images, e.g. color images from an intraoral or extraoral dental camera, such as the Gendex Concept IV series, or images acquired by digitizing film with a flatbed- scanner	VixWin Platinum is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.
Implementation	software only	Software only
Host Platform	PC	PC
Operating System	N/A	Windows 8 professional (32/64-bit)
	Windows 98, 2000, and XP ®	Windows XP professional (32-bits)
	N/A	Windows Vista Business (32-bits)
	N/A	Windows Server 2003
	N/A	Windows Server 2008
	N/A	Windows 7 Professional (32/64-bits}
Host RAM	32MB	1024 MB minimum, 2048MB recommended
Host storage	4GB minimum, 9GB or more recommended	30GB minimum, 200GB recommended
Host floppy drives	Not required	Not required
Installation Media	CD-ROM	DVD or Network
Host Processor Speed	Pentium 133 MHz, 300 MHz or faster recommended	Pentium 4 2.0 GHz min, Pentium 4 3.2 GHz recommended
Host Monitor Size	SVGA, XGA recommended	SVGA with 0.25/0.26 dot pitch
Display resolution	800 x 600 true color, 1024 x768 true color recommended	1024 x 768 24 bit true color min, 32 bit true color recommended
User Display Preferences	Yes	Yes
USB and S Video support	Yes	Yes
Receive Images from other Systems?	Yes	Yes
Images Displayed	Dental X-rays, intraoral Images	Dental X-rays, intraoral and extraoral Images
Safety Standards	Not applicable. Software only supplied	Not applicable. Software only supplied

VixWin Platinum Software has the following functionality which compares with the functionality provided for VixWin PRO predicate cleared under K060178. The functionality has been updated to remove legacy hardware no longer supported by the VixWin Platinum Software.

- Controls scanning and intake of x-ray images from imaging plates with the Photo-Stimulable Phosphor (PSP) scanners.
- Controls the direct capture of x-ray images from intra-oral sensors and extra-oral systems.
- Allows View and capture color images from intra-oral and extra-oral cameras.
- Export and import digital images (such as those obtained by scanning a film).
- Process images with dental specific tools to enhance their diagnostic value.
- Analyze and enhance images to gather additional diagnostic information which may not be immediately apparent on initial visual inspection.
- Obtaining and storing patient data pertaining to those images
- Both the viewing of the images and storage of the images and their associated data.
- Managing (locally and remotely) a database of patients and related data.
- Allows the update of existing patient information and the creation and storage of new patient information in a database over the network.
- Allows access to patient files from multiple workstations via network connectivity.
- Allows printing images and image related information over the network.

VixWin Platinum can be utilized either locally or over a networked environment. If VixWin Platinum is installed on several computers, the patient and image database can be shared among them and used from different workstations.

Substantial Equivalence

The VixWin Platinum Software with the new proposed Indications for Use described in this submission is substantially equivalent to the VixWin PRO software cleared under K0610178 and satisfy all criteria of substantial equivalence based upon the above comparisons in the sections and do not raise new concerns in safety and effectiveness: (1) Indications for Use, (2) Technological Characteristics, and (3) Theory of Operations. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is safe and effective. All internal verification and validation has been completed.

Performance Data

The current version of VixWin Platinum performs equivalently in functionality as the cleared VixWin PRO (K060178). Performance data (Verification and Validation) demonstrate that VixWin Platinum functions equivalently to the predicate devices. Thus, the VixWin Platinum (proposed) is substantially equivalent to the cleared VixWin PRO (K060178).